Risk acceptability assessment for complications of five orthopaedic procedures:

a questionnaire based study

Winifred Mukiibi

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Medicine

Johannesburg, 2024

Declaration

I Winifred Mukiibi declare that this research report in the format of a "submissible" paper is my own, unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Orthopaedic Surgery at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

……

(Signature of candidate)

On this 2nd day of May 2025 in Johannesburg

I dedicate this research work to my family and friends. To my loving husband, Daniel, for his endless support and encouragement. To my mother, Christine, who is a constant source of inspiration. To my siblings, Christine, Charles, Augustine, and Stephanie, for their unwavering support throughout this journey. Without their love and support, this project would not have been possible.

Presentations and publications arising from the research project

Podium presentation at the South African Orthopaedic Association (SAOA) Congress

Century City Convention Centre

Cape Town

4-7 September 2023

Acknowledgements

I would like to acknowledge the unwavering support of Professor Abdirashid Aden. His endless support, wealth of knowledge and guidance that he provided. You are greatly appreciated.

I would also like to acknowledge Dr Nasir Iqbal and Dr Maxwell Jingo for their guidance.

Table of contents

List of Figures

List of Tables

Nomenclature

CEO	Chief Executive Officer
CRPS	Complex regional pain syndrome
HREC	Human Research Ethics Committee
IMN	Intramedullary Nail
OA	Osteoarthritis
ORIF	Open reduction internal fixation
PI	Principal Investigator
SA	South Africa
UK	United Kingdom
USA	United States of America

“Submissible” format of a paper

Risk acceptability assessment for complications of five orthopaedic procedures: a questionnaire based study

W Mukiibi,[1] FC Orth (SA), MBChB, A.A. Aden, [1] FCS (Orth) SA, MN. Iqbal, [1] MMed (Orth), FC Orth (SA), MBChB

[1] Division of Orthopaedic Surgery, School of Clinical Medicine, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa

ABSTRACT

Background

Many orthopedic procedures are performed daily, and associated with these is always a risk of complications. A patient undergoing such a procedure must be aware of these risks. The process of informed consent is essential to achieve this. This study assessed the insight of patients close to the time of five orthopaedic procedures in our hospital. We undertook to determine the acceptable numeric thresholds for risk levels of complications of the five orthopaedic procedures that a patient may accept to give consent for a procedure. The knowledge gained will enable healthcare workers to provide better care, empower patients, and assist the judiciary system in better evaluating when dealing with malpractice cases.

Objectives

The study looked at what surgery-associated risk level a reasonable patient giving informed consent is willing to accept for five orthopaedic procedures. The study objectives were to determine the numeric risk threshold levels that are acceptable for each procedure and to describe the patients' understanding of surgery-associated risks with the five orthopaedic procedures.

Methods

The research was a descriptive study in a questionnaire format conducted at a South African tertiary hospital. There were 230 participants in the study. They had all undergone one of five orthopaedic procedures. These included femur intramedullary nailing, tibia intramedullary nailing, ankle open reduction and internal fixation, distal radius open reduction and internal fixation, and hip arthroplasty. Descriptive and analytical statistics were used to analyse the collected data.

Results

Among the total of 230 study participants across all the five procedures mentioned above, there were 124 (53.91%) participants who accepted the risk levels of all complications as reported in the literature, while 106 (46.08%) of the participants did not accept the risk level of at least one or more complications as reported in the literature. Of this same group, there were 12 (11.32%) participants who would not accept the risk level of two or more complications as

reported in the literature. For the three complications shared among some of the procedures, namely, nerve injury, infection, and malalignment/ improper implant position, there was an overall high acceptance rate of the complication risk levels, as reported in the literature. The acceptance rate was 85% for nerve injury, 91% for infection, and 97% for malalignment/improper implant position. Within the hip arthroplasty, 93.75% (n = 30) of the participants accepted the complication risk level for death as reported in the literature.

Conclusion

Patients' acceptability for the risk of the complications that can follow a surgical procedure is very important to evaluate. Almost 50% of patients who needed surgical intervention were not willing to accept the risks of one or more complications occurring with the procedure. This study has shown great variability in the acceptance levels of complication risks between the patients undergoing different orthopaedic procedures reviewed. The individualized informed consent process should be a gold standard to address the varied risk acceptance responses we found. This risk acceptance variability can be used to assist surgeons in individualizing the consent process and avoid unnecessary patient dissatisfaction and litigation.

INTRODUCTION

In the majority of orthopaedic surgeries performed yearly, many good outcomes are observed. However, as with any surgical procedure there is always a risk of a complication occurring. It is important for a patient undergoing any surgical procedure to be aware of these risks (1). There is a multitude of common or uncommon complications that can arise during surgery. These are communicated to the patient during the process of informed consent. Informed consent is a shared decision-making process that occurs between a physician and a patient (2). The surgeon must communicate adequately what the proposed surgery entails (2,3). This entails disclosure of all aspects of the suggested treatment, alternative treatment options, and discussing the nature of the proposed intervention (2,3). The discussion should include the expected benefits, material risks, adverse effects, and the consequences of not having the surgery (3,4,5). It is mandatory that all physicians fully understand the requirements of informed consent (6). Patients should also have a good understanding of the risks involved for the procedure offered (5). Appropriate information should be provided to them, in order to effectively participate in the informed consent process (3). This process has evolved to become a joint discussion in which the patient must be provided with treatment information, comprehend this information and make a sound decision based on this (4,7). The difficulty lies in determining which risks and complications are to be communicated. This was guided by the numeric percentage of the risk (1). The use of a numeric threshold provided guidance for physicians when deciding which risk needs to be communicated to patients (1,8).

It is imperative that a patient is able to consider these risks when deciding on receiving the suggested treatment (1). Previously a numeric threshold was used to determine which surgical complication risks were to be communicated to patients (1). It was understood that a high numeric threshold, justified communication of the complication risk to a patient (1). A numeric threshold is the percentage occurrence of a complication that is documented for a particular procedure (1,7). This was based on previous experiences, data and knowledge of experts in the field and is used to guide interventions (1). This threshold was used as a method to measure the likelihood of a complication occurring and help provide information to health care providers as they were in discussions with patients (7). The importance of these thresholds can be seen mostly when complications do occur and non-communication of these, is seen as negligence (8,9,10). A change can be seen from as early as 1970s, in which the courts decided

on what the acceptable standard was, when it comes to the disclosure of complications (10). This standard was previously decided by a community of physicians, and is now being decided by the courts (10). In the previous community disclosure standard, the physician and a group of colleagues decided which risks were necessary to disclose to the patient (10). In a landmark article by Wheeler et al, the concept of numeric threshold, as a guide of therapeutic care was challenged (1). This concept gained acceptance in the 1980s, by courts in Canada, when Judge Lord Bridge stated that at a 10% and above risk was to be communicated when obtaining consent (8). However, in 2004 the United Kingdom (UK) saw the case of Chester versus Afshar where a risk of 1 – 2% and above was deemed more appropriate to communicate to the patient (9). Bismark et al. also evaluated the use of numeric thresholds in the courts (8). It was later acknowledged that a risk of 1% and above the risk threshold was a good guide as necessary to communicate (8). The use of numeric thresholds can provide a reference point for a physician in their practice as well as guide judges in malpractice cases (8). Therefore, there has been a shift seen in the attitudes of physicians and the courts dealing with malpractice claims (1). Physicians were left feeling exposed and with uncertainty as to what risks are important to disclose to the patient (8).

Different types of risk groups can be described with surgical procedures. This can be separated into minor and significant risk groups. In his article, Wheeler discussed the concept of a significant risk (1). He described a significant risk as a risk that a reasonable patient may deem important to know for the decision-making process (1,3). Examples of significant risks can include death, stroke, loss of function of an organ, loss of hearing, loss of limb, and physical disability. Even though a risk may have a low occurrence rate, it can still be considered a significant risk to the patient (1,8). The details of the possible risks associated with surgery can carry different significance in different situations. An example of this is a patient in an emergency may have a higher threshold for risk acceptance, than a patient in a non-emergency situation (10). As a general guide, Bismark et al. emphasised that uncommon risks with catastrophic outcomes such as death, paraplegia, loss of sight, or loss of reproductive function, and common risks with minor adverse outcomes should all be mentioned to patients (8). In practice, it may be unreasonable to communicate a risk with a low occurrence rate to patients (1). This may scare patients and deny them the benefit of good track record procedures that may benefit them. Although this may be seen as a paternalistic approach versus a patient-centred- approach, this is the most practical thing to do. The emphasis remains that minor and

significant risks should all be mentioned (1,4). Cases describing examples of significant risks have been presented in the UK courts from as early as the 1990s (8). It was found that the need to communicate a risk of (1:2,300) for spontaneous vasectomy reversal was vital (8). In an article by Wheeler, the idea of significant risk was also brought up in an Australian court (1). The judge found a complication risk of 1:14 000 for blindness, following ophthalmic surgery was necessary to communicate to the patient (1). Depending on the type of complication risk, one may understand the rejection of a proposed treatment even when there is a known low chance of it occurring. This is further highlighted by the example of a pianist who would consider a complication that would affect their hand function as significant. Even with a low occurrence rate, this may be considered a significant complication to them and therefore should be communicated (8,10). The above-mentioned examples demonstrate that the significance a complication risk carries is based on various factors. These include the individual's requirements, the involved body part as well as their lifestyle. It carries further significance based on the importance of that said body part to the patient's livelihood and daily activities. This demonstrates that it is imperative to approach each patient based on their requirements.

The consequences of non-disclosure of a significant risk by a medical practitioner can lead to litigation and have dire consequences. This has been seen in the increasing number of medical malpractice cases seen locally in South Africa (SA) over the last 10 years (11). Similarly in America, according to a survey by the American Medical Association, 42.2% of medical practitioners are sued once and 22.4% are sued twice or more in a doctor's lifetime (12). In the same article, it is reported that 5% of these cases end up in court, and 90% of these are judged in favour of medical practitioners (12). In the 2011 study by Pepper and Slabbert, they reported that the number of wins by medical practitioners has dropped significantly over the last few years in SA (11,12). The introduction of the Consumer Protection Act in SA has widened the scope of legal liability that healthcare providers face (12). The courts hold these healthcare providers responsible for any consequence that may come from poor care (12).

Leading causes of medical malpractice cases worldwide centre around information surrounding complication risks (8). These are risks that the patient feels would have been important to communicate to them before surgery (8). It must be addressed how this can cause a dilemma for physicians, who are left with little guidance and uncertainty (13). This dilemma has called

on regulatory boards to give insight to physicians and thus guide them against the current litigation storm seen in courts (13,12). The shift in litigations cases seen, has left a magnitude of power in the hands of the courts, and minimal power with the physician. This power given to the courts is questionable, especially when it comes to understanding of medical procedures and representing patients' insights. There is a new albeit necessary emerging power that is growing with the patients. In fact, the autonomy and power of choice given to patients is definitely warranted and there is a place for a reasonable patient to make decisions about their treatment and be an active party in the process, as suggested by the courts (13). In 1972, in a case in the American courts, it was ruled that the disclosure of information should be based on what a reasonable patient needs to know and not what a reasonable physician deems necessary to disclose (8). A similar move was seen in the UK courts, when it was emphasised that a patient-centred approach with shared decision-making powers between the physician and the patient was needed (2,14). Therefore, the preferred approach is now always to uphold the patient's autonomy and provide all information that a reasonable patient would require (2,14). This way the reasonable patient and their needs are represented.

The concept of a reasonable patient standard was introduced by the courts in 2015 with the case of Montgomery versus the Lanarkshire Health Board (14). In this case, a diabetic woman in labour had the complication of shoulder dystocia. This led to the new-born baby suffering severe anoxia with subsequent cerebral palsy. (2). It was determined that the risk of shoulder dystocia was not fully communicated to the woman (14). The woman claimed that had she known this risk, she would have requested a caesarean section (2). The court ruled that the reasonable physician standard, where a physician determines what is important to be communicated should be is replaced by the reasonable patient standard, where the patient's views are recognised (2,14). The reasonable patient standard was introduced and is used widely in the courts in the UK and United States of America (USA) since then (2). This describes an objective patient who must be provided with all the information they would deem necessary to decide on undergoing treatment (2). Deficiencies with the old informed consent process that do not represent the reasonable patient have been identified. These include discussions that don't mention material risks and alternative treatment options (2). Consent forms that are generic for litigation protection purposes and written in highly technical language (2).

Before coming up with the study topic and aims, we undertook an extensive literature review dating back to the year 2000 to identify any previous or similar studies and review their findings and outcomes. Unfortunately, we found very few except one similar study. It looked at 5 possible anesthesia risks and patients' perception of these through a survey (15). Suggestions on anesthesia practice were made based on this study (15).

This study aimed to tap into the insight of the patient close to the time of five orthopaedic procedures in our hospital. We sought to determine and review the risk acceptability of complications in these orthopaedic procedures. With this, we aimed to determine the numeric thresholds of complications for five common orthopaedic procedures and therefore be able to describe what level of threshold is acceptable to a patient who has undergone one of the said orthopaedic procedures. The study looked at what surgery-associated risk level; a reasonable patient giving informed consent is willing to accept for five orthopaedic procedures. We hope that this insight will enable healthcare workers to provide better care, empower patients, and assist the judiciary system in better navigating when dealing with the multiple malpractice cases they face daily.

METHODS

Study Design

This was a descriptive study in a survey format conducted at a tertiary South African hospital (Helen Joseph Hospital). The Chief Executive Officer (CEO) and the Head of the Orthopaedic Surgery Department granted permission to conduct the study. Ethics approval was granted by the Human Research Ethics Committee (HREC) of the University of the Witwatersrand (clearance no: M210876).

Participants and materials

All patients who presented to the HJH orthopaedic department from the period 01 November 2021 to 31 April 2022 were considered for the study. These are patients who were admitted for either elective or emergency surgeries to the orthopaedic department. Data collected was through a questionnaire format conducted with participants. An initial pilot study was conducted to assess the ideal method of conducting the questionnaire and understanding of the

questions asked. This assisted in identifying any issues with format and execution. This showed the need for better explanation of complications to participants, to ensure understanding. A patient who met our inclusion criteria was approached in the ward to join the study from day 1 to 3 post-operatively. Each participant was given a study number and identifying information was left anonymous. The principal investigator (PI) (Dr Mukiibi) administered questionnaires to participants post-operatively. Being able to communicate in most local languages known to the area, an interpreter was not used. The questionnaire included demographic information, information on the surgical procedures and associated surgical risk factors. Provided is the study consent form and study questionnaire (Appendix A and B). Participants were shown a table depicting general life experiences risks, to better help them understand and interpret the complication risk values stated in the questionnaire (Appendix C). Possible complications were assessed with each procedure group. The participants provided their acceptable risk value with each complication provided.

We debated as to the best time to collect data in relation to the time of the operation. Interviewing a person who had no health problem was ruled out since their mindset cannot match that of someone who needs surgery. Likewise, interviewing patients who developed complications was also ruled out since they would be strongly biased. Since interviewing all patients before the operations is practically impossible for a single researcher, an interview with these patients soon after the procedure within 72 hours post-surgery while they still can remember their consent was considered plausible and feasible. Participants were approached from the patients who presented to the orthopaedic department and met all inclusion criteria.

Inclusion criteria included the following: males and females above the age of 18 years who had given informed consent. Patients undergoing one of the following five orthopaedic surgical procedures – femur intramedullary nailing (IMN), tibia intramedullary nailing (IMN), ankle open reduction and internal fixation (ORIF), distal radius open reduction (ORIF) and hip arthroplasty procedures were also included. Exclusion criteria included: patients who were not able to give informed consent for the research study, patients with an altered level of consciousness, polytrauma patients, patients with a language barrier, a patient with an existing complication post-surgery and patients who were more than 72 hours post-surgery.

Participant's questionnaire sheets were assigned unique study numbers to maintain anonymity and confidentiality. The PI carried out a questionnaire-based interview with the participants. A table with complications of planned orthopaedic procedures and literature stating the risk level percentage was shared. Complications selected for each procedure were widely known or significant complications (Table 2). Participants then selected what level of risk for each complication they would accept. The responses on the questionnaire interview sheet were used to collect data that was later reviewed using statistical measures. The data collected was used to interpret the patterns among the participants' responses and answer the research question. The assistance of a biostatistician was used, and data were analysed with the use of STATA version 17 with descriptive and analytical analysis done. Statistical significance was set at $p < 0.05$. The PI kept the completed data collection sheets safe on a password-protected computer.

RESULTS

We included 230 participants in the study 70.86% (n = 163) male and 29.13% (n = 67) female (Fig. 1). The mean age of participants was 48 +- 18.05 years old. The education breakdown of the participants was: no education background 13.47% (n = 31); primary school level 31.30% (n = 72); high school level 33.04% (n = 76) and tertiary level 22.17% (n = 51) (Table 1). Racial breakdown was 64.78% (n = 149) Black race; 12.60% (n=29) White race; 16.09% (n = 37) Coloured; 4.35% (n = 10) Indian and 1.74% (n = 4) Chinese (Table 1). Employment status consisted of 66.08% (n = 152) unemployed at the time of the questionnaire; 23.04% (n = 53) were blue-collar workers and 10.86% (n = 25) were white-collar workers. Five orthopaedic procedures were included: 65 femur IMN, 52 tibia IMN, 45 ankle ORIF, 36 distal radius ORIF and 32 hip arthroplasty (Table 1).

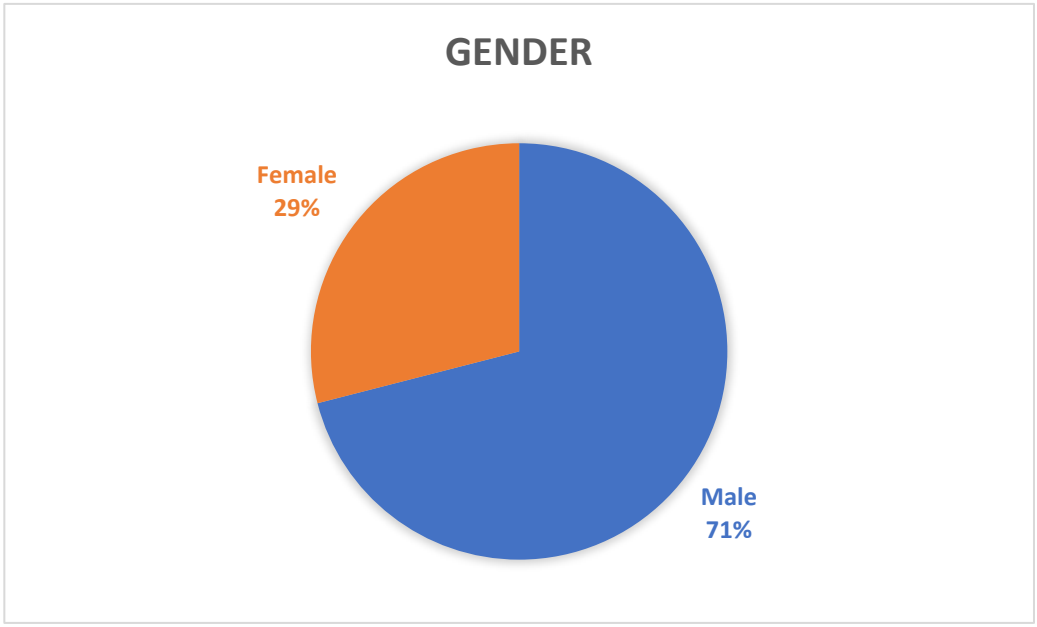

Fig. 1. Gender Distribution

Table 1. Summary statistics by sex, *n* = 230

	Female (N = 67)	Male (N = 163)	Total (N = 230)	p-value
Age category (years)				0.001
40 or less	17 (25.4%)	82 (50.3%)	99 (43.0%)	
41 to 60	22 (32.8%)	45 (27.6%)	67 (29.1%)	
61+	28 (41.8%)	36 (22.1%)	64 (27.8%)	
Racial group				0.784
Black	42 (62.7%)	107 (65.6%)	149 (64.8%)	
Coloured/Indian	13 (19.4%)	34 (20.9%)	47 (20.4%)	
Other	2 (3.0%)	3 (1.8%)	5 (2.2%)	
White	10 (14.9%)	19 (11.7%)	29 (12.6%)	
Education				0.002
High school	19 (28.4%)	57 (35.0%)	76 (33.0%)	
None	2 (3.0%)29	(17.8%)	31 (13.5%)	
Primary	24 (35.8%)	48 (29.4%)	72 (31.3%)	
Tertiary	22 (32.8%)	29 (17.8%)	51 (22.2%)	
Procedure				0.001
Ankle ORIF	14 (20.9%)	31 (19.0%)	45 (19.6%)	
Distal radius ORIF	13 (19.4%)	23 (14.1%)	36 (15.7%)	
Femur	15 (22.4%)	50 (30.7%)	65 (28.3%)	
Arthroplasty	18 (26.9%)	14 (8.6%)	32 (13.9%)	
Tibia IMN	7 (10.4%)	45 (27.6%)	52 (22.6%)	
Diagnosis				0.001
Ankle fracture	14 (20.9%)	31 (19.0%)	45 (19.6%)	
Distal radius fracture	13 (19.4%)	23 (14.1%)	36 (15.7%)	
Femur fracture	15 (22.4%)	49 (30.1%)	64 (27.8%)	
NOF	7 (10.4%)	6 (3.7%)	13 (5.7%)	
OA	11 (16.4%)	8 (4.9%)	19 (8.3%)	
Tibia fracture	7 (10.4%)	46 (28.2%)	53 (23.0%)	
Day post- surgery				0.929
Day 1	26 (38.8%)	66 (40.5%)	92 (40.0%)	
Day 2	28 (41.8%)	63 (38.7%)	91 (39.6%)	
Day 3	13 (19.4%)	34 (20.9%)	47 (20.4%)	
Surgical category				0.003
Elective	12 (17.9%)	8 (4.9%)	20 (8.7%)	
Emergency	55 (82.1%)	155 (95.1%)	210 (91.3%)	

Among the total of 230 study participants across all the five procedures and their complication (Table 2) responses were reviewed, there were 124 (53.91%) participants who accepted the risk levels of all complications as reported in the literature, while 106 (46.08%) of the participants did not accept the risk level of at least one or more complications as reported in the literature (Fig. 2). Of this same group, there were 12 (11.32%) participants who would not accept the risk level of two or more complications as reported in the literature. A positive finding was that none of the participants, across all procedure groups, would not accept all of the 4 complication risk levels as reported in the literature.

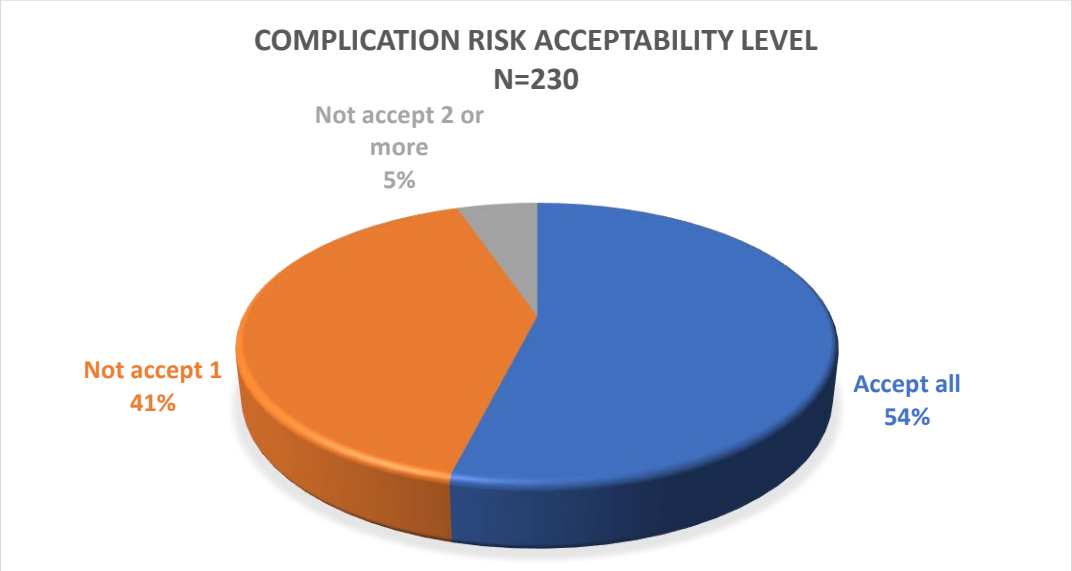

Fig. 2. Total participants risk acceptability and non-acceptability as per literature

Table 2. Procedures and complications

Femur IMN	Tibia IMN	Ankle ORIF	Distal radius ORIF	Hip arthroplasty
Nerve injury	Infection	OA	Tendon injury	Nerve injury
Muscle injury	Compartment Syndrome	Thromboembolism	Nerve injury	Dislocation
Hip pain	Knee pain	Infection	CRPS	Infection
Malalignment/ Improper implant position	Non-union	Malalignment/ Improper implant position	Malalignment/ Improper implant position	Death

Within the femur IMN group, 46.15% (*n* = 30) accepted the risk level of complications as reported in the literature, and 53.85% (*n* = 35) did not accept the risk level of one or more complications as reported in the literature. From this group that did not accept, 82.86% (*n* = 29) would not accept one complication risk level, and 17.14% (*n* = 6) would not accept two or more risk levels of complication as reported in the literature. Among this group, 65.72% (*n* = 23) were above the age of 40 years, and 62.86% (*n* = 22) were unemployed at the time of the questionnaire (Table 3).

Within the tibia IMN group, 57.69% (*n* = 30) accepted the risk level of complications as reported in the literature, and 42.31% (*n* = 22) did not accept the risk level of one or more complications as reported in the literature. From this group that did not accept, 86.36% (*n* = 19) would not accept one complication risk level, and 13.63% (*n* = 3) would not accept two or more risk levels of complication as reported in the literature. Among this group, 72.73% (*n* = 16) were of black race, and 72.73% (*n* = 16) were unemployed at the time of the questionnaire (Table 4).

Within the ankle ORIF group, 55.56% (*n* = 25) accepted the risk level of complications as reported in the literature, and 44.44% (*n* = 20) did not accept the risk level of one or more complications as reported in the literature. From this group that did not accept, 85% (*n* = 17) would not accept one complication risk level, and 15% (*n* = 5) would not accept two or more risk levels of complication as reported in the literature. Among the group, 75% (*n* = 15) were of black race, and 75% (*n* = 15) were unemployed at the time of the questionnaire (Table 5).

Within the distal radius ORIF group, 69.44% (*n* = 25) accepted the risk level of complications as reported in the literature, and 30.56% (*n* = 11) did not accept the complication risk as per the literature. From this group that did not accept, 90.91% (*n* = 10) would not accept one complication risk level, and 9.09% (*n* = 1) would not accept two or more risk levels as reported in the literature. In the group that did not accept risk level as per literature, 72.73% (*n* = 8) were below the age of 40 years, 63.64% (*n* = 8) of black race and 81.82% (*n* = 9) were unemployed at the time of the questionnaire (Table 6).

Table 3. Femur IMN complication groups and acceptability

Complication	Nerve Injury	Muscle Injury	Hip pain	Malalignment/ Improper implant position
Accept	59	35	63	61
Not accept	6	30	2	4

Table 4. Tibia IMN complication groups and acceptability

Complication	Infection	Compartment syndrome	Knee pain	Non-union
Accept	46	47	44	48
Not accept	6	5	8	4

Table 5. Ankle ORIF complication groups and acceptability

Complication	OA	Throboembolism	Malalignment/ Improper implant position	Infection
Accept	30	41	43	35
Not accept	13	2	0	8

Table 6. Distal radius ORIF complication groups and acceptability

Complication	Tendon Injury	Nerve Injury	CRPS	Malalignment/ Improper implant position
Accept	33	33	37	37
Not accept	5	5	1	1

Within the hip arthroplasty group, 37.5% (*n* = 12) accepted the risk level of complications as reported in literature and 62.5% (n = 20) did not accept the complication risk as per literature. From this group that did not accept 85% (*n* = 17) would not accept one complication risk level and 15% (*n* = 3) would not accept two or more risk levels as reported in the literature. There were 55% (*n* = 11) presenting with neck of femur fractures and 45% (*n* = 9) presenting with

hip osteoarthritis in this group. Furthermore, the group consisted of 95% (*n* = 19) who were above the age of 40 years, 45% (*n* = 9) had primary school level as their highest level of education 70% (*n* = 14) were unemployed at the time of the questionnaire (Fig. 3, Table 7).

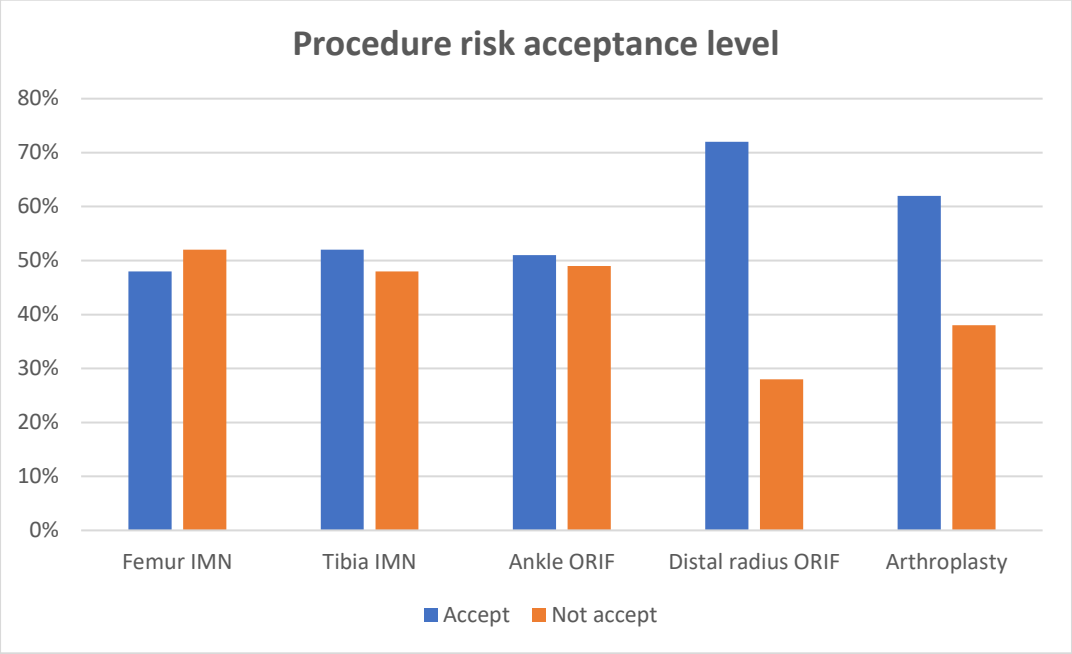

Fig. 3. Procedures and complication acceptability risk groups

Table 7. Arthroplasty complication groups and acceptability

Complication	Nerve Injury	Dislocation	Infection	Death
Accept	22	24	29	30
Not accept	10	8	3	2

Complications that were shared amongst the different procedure groups were analysed. These included nerve injury, infection, and malalignment/improper implant position. These three complications are significant to the orthopaedic surgeon and patient. Nerve injury can significantly affect the functioning of a limb and is often a complex injury to remedy. Infection is a devastating complication that is complex to manage. Malalignment/improper implant position of implants is not a desired outcome for both the surgeon and the patient. Nerve injury was reviewed as one of the complications that were included in the procedure groups: femur IMN, distal radius ORIF, and hip arthroplasty. This was a total of 137 participants. We found

that 84.67% (*n* = 116) of this group accepted the complication risk level as reported in the literature, and 15.32% (*n* = 21) did not accept the complication risk level as reported in the literature. Infection was also reviewed as one of the complications for group procedures: tibia IMN, arthroplasty, and ankle ORIF. This included 190 participants, and of this group, 91.05% (*n* = 173) accepted the complication risk level as reported in the literature, and only 8.89% (*n* = 17) did not accept the risk level as reported in the literature. The malalignment/improper implant position complication was reviewed in the femur IMN, ankle ORIF, and distal radius ORIF groups. This included 146 participants. From this group, 96.57% (*n* = 141) accepted the complication risk level as reported in the literature, and only 3.42% (*n* = 5) did not accept the complication risk level as reported in the literature (Fig. 4).

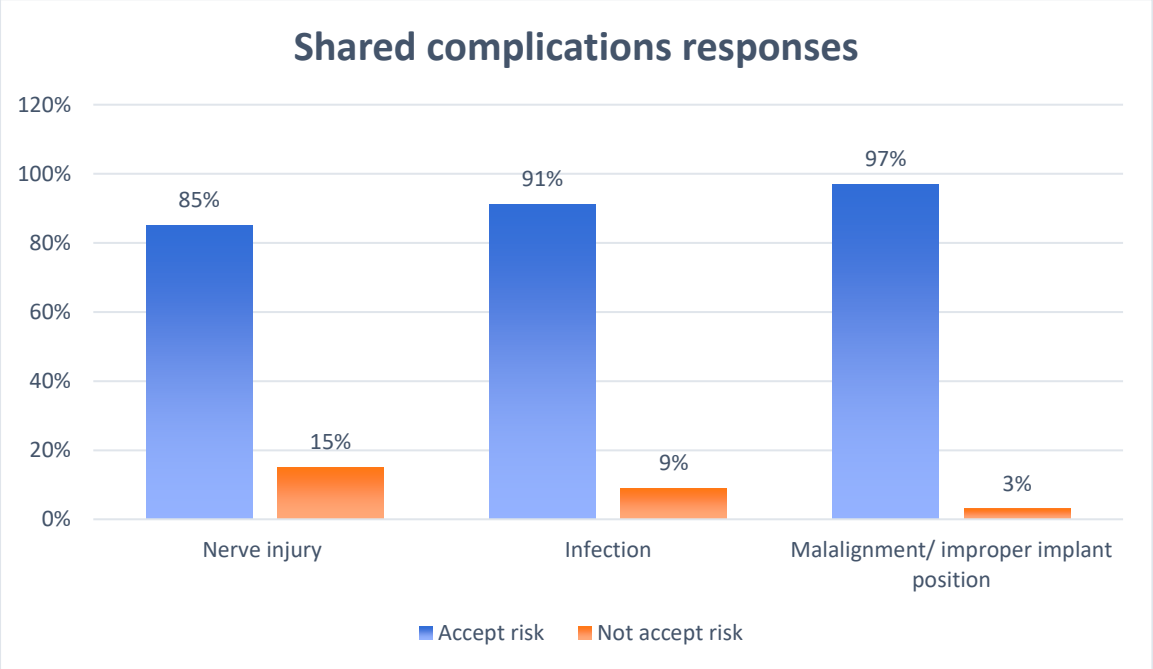

Fig. 4. Shared complications groups patient responses

Significant complications such as death were included in the hip arthroplasty group. This group consisted of a total of 32 participants. A significant amount of 93.75% (*n* = 30) of participants accepted the complication risk level for death as reported in the literature. The participants in this group were above the age of 51 of age with the mean age being 65 ± 13.01 years old. There were 6.25% (*n* = 2) that did not accept the risk level as reported in the literature. The complication of complex regional pain syndrome (CRPS) was included for distal radius ORIF. There were 36 participants in this group with 97.22% (*n* = 35) accepting the complication risk

level as per literature and only 2.78% (n = 1) of participants not accepting the level as per literature. The group that accepted was 66.67% (*n* = 24) of the black race and 63.89% (*n* = 23) unemployed at the time of the questionnaire. The one participant who did not accept risk level as per literature had a primary school as the highest level of education and was unemployed at the time of the questionnaire. Compartment syndrome was included as a complication for tibia IMN. For this group, 90.38% (*n* = 47) accepted complication risk levels as per the literature, and 68.09% (*n* = 32) were below the age of 40 years. Education level was either high school level of education at 36.17% (*n* = 17) or primary level at 34.04% (*n* = 16). There were 68.09% (*n* = 32) of participants unemployed at the time of the questionnaire.

The complication risk levels reported as per the literature and with the highest acceptability were reviewed for each procedure. For femur IMN, it was hip pain at 96.92% (*n* = 63); for tibia IMN, it was non-union at 92.31 % (*n* = 48); for ankle ORIF, it was malalignment/improper implant position at 100% (n = 45); for distal radius ORIF, it was CRPS at 97.22% (*n* = 35) and malalignment/improper implant position at 97.22% (*n* = 35) and for hip arthroplasty, it was death at 93.75% (*n* = 30). The complication risk levels reported as per the literature and with the lowest acceptability were reviewed for each procedure. For femur IMN, it was muscle injury at 46.15% (*n* = 30); for tibia IMN, it was infection at 11.54% (*n* = 6); for ankle ORIF, it was osteoarthritis (OA) at 28.89% (*n* = 13); for distal radius ORIF, it was nerve injury at 13.89% (*n* = 5) and tendon injury at 13.89% (*n* = 5) and for hip arthroplasty, it was nerve injury at 31.25% (*n* = 10).

DISCUSSION

Patients' acceptability for the risk of the complications that can follow a surgical procedure is very important to evaluate. The insight into a reasonable patient may prove valuable in surgical practice. A reasonable patient standard was introduced, and is used widely in the courts. In the previous paternalistic practice seen in courts. The insights of what a prudent doctor would have done as opposed to what a reasonable patient would want to know, was the practised standard (14). There has been a move from the previous paternalistic standard to a patient-centred approach. Accordingly, a patient must be informed of almost all risks and possible alternatives before agreeing to treatment (14). This counters cases where a patient may say "If I would have been told about that complication, I would never have agreed to surgery".

Within the different procedure groups included in the study, we found that 2/3 of participants accepted higher risk levels than those stated in the literature, and half accepted lower risk levels than those stated in the literature. For the three complications shared among some of the procedures, namely, nerve injury, infection, and malalignment/ improper implant position, there was an overall high acceptance rate of the complication risk levels, as reported in the literature. The acceptance rate was 85% for nerve injury, 91% for infection, and 97% for malalignment/improper implant position. This may be attributed to the patient's perception that these are non-permanent states that may follow the surgical procedure. It may also be attributed to the patient's understanding that these complications can be addressed, resulting in favourable outcomes. CRPS in the distal radius ORIF group and compartment syndrome in the tibia IMN group were also reviewed. Within these complication groups, there were higher levels of complication risk acceptability than those stated in the literature. This was 97.22% for CRPS and 90.38% for compartment syndrome. This could be due to a poor understanding of the concepts of CRPS and compartment syndrome by the study participants. In a situation where there is poor understanding of a complication, the participant would accept the risk due to little insight and the promise of fracture fixation. There were more than 2/3 of patients that accepted the risk level of malalignment / improper implant position as stated in literature within the distal radius ORIF group. This can be attributed to the knowledge that an improper placement of an implant during surgery can always be rectified by a revision surgery. Such a complication can have a solution to address the issue, thereby sometimes causing minimal permanent effects. Within the femur IMN group, almost half of the patients accepted lower

than the risk level as per literature for muscle injury. This may be due to a lack of understanding that an injury to a muscle has the potential to heal versus permanent damage to the muscle. Within the tibia IMN group, we found that 2/3 of the patients accepted a higher risk figure for infection than that reported in the literature. This can be explained by patients' understanding that should infection occur, something could be done to rectify it. This may also be due to an understanding that an infected united bone is better than a broken one.

In the hip arthroplasty group, the risk of surgery-related death was accepted by more than 2/3 of the patients as per the literature. More than half of this group that accepted to take the risk of death presented with hip osteoarthritis. This is a significant amount that must be highlighted. This group consisted of patients with an average age of 65 ± 13.01 years old, and all had a primary or higher level of education. However, education was not found to be a good discriminator across the board. Nearly similar figures were found in acceptance levels between patients with different levels of education. There were more than 1/3 who accepted even more than the risk level as per the literature. However, two patients did not accept the death risk levels as per the literature. They were 38 and 39 years old, both with neck of femur fractures, and had primary and high school levels of education, respectively. This can be explained by the information that the hip arthroplasty group consisted of two groups- patients with OA hip and those with a neck of femur fracture. The group with OA hip were elderly patients who had a long, ongoing experience of pain that affected activity. Perhaps when one is elderly and in chronic pain, they are more willing to take the risk of death to end the pain. This is in contrast to a young patient, who is less likely to accept the chance of death as it is an idea that is far from their current stage in life. The question to ask is, what would one offer such a patient? Similarly, in the ankle ORIF, there was a high acceptance of osteoarthritis by 2/3 of the patients. This may be due to a poor understanding of the complication. It may also be attributed to their understanding that it is a treatable condition.

Almost 50% of patients who needed surgical intervention were not willing to accept the risks of one or more complications occurring with the procedure. This is a substantial number, and it is worrisome. This may be due to a lack of grasp of the concept of what the percentage risk for the complication means. It may also be due to a lack of understanding of the complication itself and fear of the unknown. It may also arise from the inability to compare the present

situation with the situation that a complication may bring. Finally, a patient may have the hope that something may change with the current situation or that another surgeon may offer a risk level better accepted. In any way, this certainly highlights how much work is needed to put into developing effective consent-taking behaviours.

CONCLUSION

This study has shown great variability in the acceptance levels of complication risks between the patients undergoing different orthopaedic procedures reviewed. Almost half of the patients would not accept one or more of the complication risk levels, which is a significant number. Different patients with the same surgical problem and undergoing the same surgical procedure can have different outlooks on the risk levels they are prepared to take. Some accepted to take more risk, while others accepted minimal risk. Our patient population consisted of a variety of demographics including age, cultural backgrounds, educational levels, and employment status. We found that the responses of patients when presented with the risk of a complication varied. This did not show any trend with demographics such as age, race, or level of education. The importance of an individualized consent process is of paramount importance in the consent-taking process. This may address the variation in risk acceptability levels that is seen. The concept of a reasonable patient standard that is referred to is not a tangible one. Therefore, to be used as a benchmark for all patients is not practical. This concept is used in courts, where a judge determines what this reasonable patient standard is. This is a questionable standard and perhaps not something that can be decided in isolation by one person. However, it has been shown that the reasonable patient standard is still superior to the reasonable doctor standard. It can even be said that in such cases, the most objective view would be one from someone in the same position and going through the same experience. The individualized informed consent process should be a gold standard to address the varied risk acceptance responses we found. This risk acceptance variability can be used to assist surgeons in individualising the consent process and avoid unnecessary patient dissatisfaction and litigation.

RECOMMENDATIONS

- Given the high number of patients who would not accept the complication risk associated with surgical procedures when obtaining informed consent and discussing the complications associated with a procedure, it is recommended that a detailed explanation of the complications and their outcomes is given to the patient. The possibility of rectification and recovery from a complication should also be addressed. This may increase the acceptance of risk levels of a patient undergoing a surgical procedure.
- The group of patients that would not accept risk levels of complications, as reported in the literature, have to be handled appropriately. One may repeat the explanation with further expansion. A conversation with the patient in a group of doctors and the involvement of relatives and loved ones in the discussion may also help. Allowing patients to ask and further enquire while giving them time to think about the procedure is also another suggestion. However, explaining the caution that will be taken to avoid any complications perhaps may assist well.
- A follow-up study of this above-mentioned group is needed. It is worthwhile to study the mindset of this group as well as what motivates their attitude and leads them to refuse the risk associated with the treatment of their orthopaedic problem. This study can also look at the impact of the above suggestions on the patients' views and the possibility of helping them to change their minds.
- This study can be further extended to include more orthopaedic surgery procedures.

REFERENCES

1. Wheeler R. The numeric threshold for disclosure risk: outdated and inapplicable to surgical consent. Ann R Coll Surg Engl. 2012; 94: 81-82.
2. Spatz E, Krumholz H and Moulton B. The New Era of Informed Consent: Getting to a Reasonable- Patient Standard Through Decision Making. JAMA. 2016; 315(19): 2063-2064.
3. Hanson M and Pitt D. Informed consent for surgery: risk discussion and documentation. Can J Surg. 2017; 60 (1):69-70.
4. Ellamushi HE, Khan R and Kitchen ND. Consent to surgery in a high-risk specialty: a prospective audit. Ann R Coll Engl. 2000; 82:213-216.
5. Uzbeck M et al. Randomised controlled trial of the effect of standard and detailed risk disclosure prior to bronchoscopy on peri-procedure anxiety and satisfaction. Thorax. 2009; 64:224-227.
6. Paterick et al. Medical Informed Consent: General Considerations for Physicians. Mayo Clin Proc. 2008; 83(3): 313-319.
7. National Health Act, 2003. Act No. 61 of 2003. Government Gazette. Vol 469 No. 26595.
8. Bismark M et al. Legal Disputes over Duties to Disclose Treatment Risks to Patients: A Review of Negligence Claims and Complaints in Australia. 2012. PLOS Med. 2012; 9(8):e1001283.
9. Rajab T, Ahmad U and Kelly E. Implications of late complications from adhesions for preoperative informed consent. J R Soc Med. 2010; 103: 317-321.
10. Murray B. Informed Consent: What Must a Physician Disclose to a Patient? American Med Assoc J of Ethics. 2012; 14(7): 563-566.
11. Seggie J. The 'boom' in medical malpractice claims- patients could be losers. S Afr Med J. 2013; 103(7):433.
12. Pepper M and Slabbert M. Is South Africa on the verge of a medical malpractice litigation storm? SAJBL. 2011; 4(1): 29-35.
13. Davaney S et al. The far-reaching implications of Montgomery for risk disclosure in practice. J of Patient Safety and Risk Mgmt. 2019; 24(1): 25-29.
14. Kelvin et al. The conundrums of the reasonable patient standard in English medical law. 2023. BMC Medical Ethics. 2023; 24(15):1-15.
15. Burkle C.M. et al. Patient fear of anaesthesia complications according to surgical type: potential impact on informed consent for anaesthesia. Acta Anaesthesiol Scand 2014; 58: 1249-1257.

Appendices:

Appendix A: Consent form

At what Percentage of a risk would a patient who is undergoing an Orthopaedic procedure, be sure to withhold consent for that surgery?

Consent to take part in research

- I……..voluntarily agree to participate in this research study.
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind.
- I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me and I have had the opportunity to ask questions about the study.
- I understand that participation involves anonymously participating in an interview, where I will be asked questions and these answers recorded.
- I understand that I will not benefit directly from participating in this research.
- I understand that all information I provide for this study will be treated confidentially.
- I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.
- I understand that signed consent forms, questionnaires and original data sheets will be retained by the researchers.
- I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

Dr Winifred Mukiibi , MBChB (UCT), FCOrth (SA)

Name of Participant:

Signature of participant:

Date :

I believe the participant is giving informed consent to participate in this study

Signature of researcher:

Date:

Appendix B: Questionnaire

Case No.

Demographics

1. Gender

☐ Male ☐ Female

Other (please specify) ☐

2. Age. ☐

3. Race

☐Black ☐White ☐Coloured ☐ Indian ☐Other

4. Occupation

☐Unemployed

☐Employed

☐White collar (office/professional worker)

☐Blue collar (manual labourer/worker)

☐Tertiary Student

☐Housewife

5. Highest level of Education

☐Primary school ☐High school ☐Tertiary ☐ None

Surgery Section

6. Diagnosis

☐

7. Procedure

☐

8. Surgical category

☐Elective ☐Emergency

9. Who gave consent for surgery?

☐Patient ☐Proxy

10. What procedure did you consent for?

☐

11. Interval between consent and surgery.

☐Day of surgery ☐ Day 1 post-surgery ☐ Day 2 post-surgery ☐ Day 3 post-surgery

Femur Intramedullary Nail

Surgical Complications

Which of these complications associated with your operation are you aware of?

☐Nerve Injury ☐None

☐Muscle injury

☐Hip pain

☐Malalignment

☐ ☐Death

Which risk rating percentage would you find acceptable for each complication?

Complication	Participants Figure 0-100%	Literature Figure	Do you accept literature figure? Yes / No
Nerve injury		1-2%	
Muscle injury		80-85%	
Hip pain		5-10%	
Malalignment/ improper implant position		10-15%	

1. *Papachristos I. Complications of Femoral Intramedullary Nailing: What should the Surgeon remember. EC Orthopaedics. 2019.*

2. *Moghtadaei M et al. Risk of Superior Gluteal Nerve Injury After Using Ante-Grade Femoral Nailing. Biomedical and Pharmacology Journal. 2016.*

Tibia Intramedullary Nail

Surgical Complications

Which of these complications associated with your operation are you aware of?

☐ Knee pain

☐ Non-union

☐ Infection

☐ Compartment syndrome

☐ Death

☐ None

Which risk rating percentage would you find acceptable for each complication?

Complication	Participants Figure 0-100%	Literature Figure	Do you accept literature figure? Yes / No
Infection		1-2%	
Compartment syndrome		10-15%	
Knee pain		15-20%	
Non-union		5-10%	

1. *Si Young S et al. Anterior knee pain after tibial intramedullary nailing using a medial paratendinous approach. Journal of Orthopaedic Trauma. 2012.*
2. *Catalin L et al. Tibial nailing causes compartment syndrome compared with external fixation in acute closed tibial fractures. Techniques in Orthopaedics. 2014.*
3. *Dalley H et al. Tibial fracture nonunion and time to healing following reamed intramedullary nailing: Risk factors based on a single-centre review of 1003 patients. Journal of Orthopaedic Trauma. 2018.*

Ankle open reduction internal fixation

Surgical Complications

Which of these complications associated with your operation are you aware of?

☐Osteoarthritis ☐None

☐Loss of reduction

☐Thromboembolism / Blood clots

☐Infection

☐Death

Which risk rating percentage would you find acceptable for each complication?

Complication	Participants Figure 0-100%	Literature Figure	Do you accept literature figure? Yes / No
Osteoarthritis		35-40%	
Thromboembolism / Blood clots		2-3%	
Malalignment/ Improper implant position		1-2%	
Infection		5-10%	

1. *Lubbeke A et al. Risk factors for post-traumatic osteoarthritis of the ankle: an eighteen year follow-up study. International Orthopaedics (SICOT). 2012.*

2. *Leyes M & Torres R. Complications of open reduction and internal fixation of ankle fractures. Foot and Ankle Clinics. 2003.*

Distal radius open reduction internal fixation

Surgical Complications

Which of these complications associated with your operation are you aware of?

☐ Tendon injury ☐ None

☐ Nerve injury

☐ CRPS

☐ Screw penetration / Screw too long

☐ Death

Which risk rating percentage would you find acceptable for each complication?

Complication	Participants Figure 0-100%	Literature Figure	Do you accept literature figure? Yes / No
Tendon injury		15-20%	
Nerve injury		4-8%	
CRPS		10-15%	
Screw penetration / Screw too long		2-3%	

1. *Seigerman D et al. Complications in the Management of Distal Radius Fractures: How Do We Avoid them? Current Reviews in Musculoskeletal Medicine. 2019.*
2. *Partap A et al. Flexor policis tendon rupture after volar plating of distal radius fracture. Journal of Orthopaedics and Sports Medicine. 2020.*
3. *DeGeorge B et al. Management of distal radial fractures in the elderly. The Journal of Bone and Joint Surgery. 2020.*

Hip arthroplasty

Surgical Complications

Which of these complications associated with your operation are you aware of?

☐ Dislocation

☐ Nerve injury

☐ Infection

☐ Death

☐ None

Which risk rating percentage would you find acceptable for each complication?

Complication	Participants Figure 0-100%	Literature Figure	Do you accept literature figure? Yes / No
Nerve injury		2-4%	
Dislocation		2-3%	
Infection		1-2%	
Death		0.5- 1%	

1. *Hansen E. Total hip replacement surgery risks and complications. Arthritis health. 2020.*
2. *Hasija R et al. Nerve injuries associated with total hip arthroplasty. Journal of Clinical Orthopaedics and Trauma. 2017.*

Appendix C

This table is to be used as a reference for comparison of surgical risks and normal life experiences.
The examples used will help you better understand the ratios used in the questionnaire. Risks are shown from common to rare risks (15).

Incidence/Ratio	Surgical Risk	Life experiences
Common 1:4	Knee pain following tibia nail surgery	Being involved in a car accident in your lifetime
Fairly common 1:100	Infection following arthroplasty surgery	Dying after being involved in a motor vehicle accident
Rare 1:1000	Peripheral nerve injury	Dying from accidental drowning

Appendix D

Ethics clearance certificate

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R49 Dr W Mukiibi

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M210876

NAME: (Principal Investigator)	Dr W Mukiibi
DEPARTMENT:	School of Clinical Medicine Department of Orthopaedics Medical School University
PROJECT TITLE:	*Risk acceptability assessment for complications of five orthopaedic procedures: a questionnaire-based study*
DATE CONSIDERED:	2021/08/27
DECISION:	Approved unconditionally
CONDITIONS:	
NOTE:	If contact information regarding student study participants is required, please contact the Registrar's office - <Nicoleen.Potgieter@wits.ac.za>
SUPERVISOR:	Professor A Aden
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2021/10/18

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in August and therefore reports and re-certification will be due in the month of **August** ea[illegible] ed changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator

22/10/2021
Date

Appendix E

Hospital permission letter

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Gauteng Department of Health
Helen Joseph Hospital
Enquiries: Dr. M. Mukansi
Research Committee: Chairperson
Tel :(011) 489-0306/1087
Fax :(011) 489 1038
E mail:Murimisi.mukansi@wits.ac.za

07 July 2021

To whom it may concern

Subject: HELEN JOSEPH HOSPITAL RESEARCH COMMITTEE APPLICATION

PROTOCOL TITLE: At what percentage of a risk would a patient who is undergoing an Orthopaedic procedure be sure to withhold consent for that surgery?

Principal Investigator: Winifred Mukibi

Ethics Clearance: Pending

Co- investigator: Winifred Mukibi

Department: Helen Joseph Hospital

Committee Recommendations
The Committee is giving you Conditional access while awaiting the final ethical clearance certificate from the University of Witwatersrand HREC.

It is the duty of the researcher to collect the data to the relevant department after the Research Committee approved the study.

Dr. M. Mukansi
Chairperson of HJH Ethic and Research Committee

Appendix F

Student's contribution to the research and writing of the "submissible" paper

Division of Orthopaedic Surgery

Faculty of Health Sciences, 4M Room 12, Wits Medical School, 7 York Road, Parktown 2193
Tel: +27 11 717-2538 Fax: +27 11 717-2551

12/12/2024

Faculty of Health Sciences, University of the Witwatersrand

RE: WINIFRED MUKIIBI'S CONTRIBUTION TO THE RESEARCH AND WRITING OF THE "SUBMISSIBLE" PAPER

To whom it may concern,

This letter serves to confirm that the co-authors of the "submissible" research paper have agreed to its use by Winifred Mukiibi, student number: 2447979, as part of her MMed research report. Winifred Mukiibi made a substantial contribution to conducting the research study and writing the manuscript.

Yours sincerely,

……

Professor Abdirashid Aden

Primary Supervisor

……

Winifred Mukiibi

MMed Candidate